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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,343

03/17/2006

Richard Isaacs

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210 7590 06/11/2009
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EXAMINER

DAVIS, ZINNA NORTINGTON

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

06/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/572,343	Applicant(s) ISAACS ET AL.	
	Examiner Zinna Northington Davis	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 8-18 and 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 19 and 20 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/12/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-23 are pending.
2. In the response filed March 27, 2009, Applicants have elected Group I, claims 1-7, 19 and 20, without traverse. Applicants also identify the compound of Formula I wherein A is 3-fluorophenyl, R¹ is H, R² is H, R⁵ is -C(O)OR⁵⁵, R⁵⁵ is H, R⁸ is H, R⁹ is OR⁴³, wherein R⁴³ is C1-C6 alkyl and R¹⁰ is H as the preferred species.
3. Claims 8-18 and 21-23 are withdrawn from consideration.
4. Rejoinder of the method claims will be addressed upon allowance of claimed subject matter.
5. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).
6. Claims 1-7, 19, and 20 are Markush claims which are generic to the elected invention. These Markush claims lack unity of invention. Accordingly, the Markush type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. See MPEP 803.02.
7. Claims 1-7, 19, and 20 are objected on the grounds that the claims are drawn to an improper Markush group. In re Harnisch, 206 USPQ 300, states that a unity of invention exists where compounds included within a Markush group(1) share a common

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utility and (2) share a substantial structural feature disclosed as being essential to that utility. In the instant case, the claimed subject matter does not share a substantial structural feature disclosed as being essential to that utility.

8. The requirement for a proper Markush claim is that it includes only substances that in their physical, chemical and physiological characteristics are functionally equivalent. The members of the instant Markush groups possess widely different, physical and chemical properties. The compounds are not considered functionally equivalent and are so diverse that they demonstrate dissimilar and unrelated properties. The mere fact that there is structural similarity in pharmaceutical agents is not in itself reason to render all the embodiments functionally equivalent.

9. The improper Markush groups are A, R⁵, R², R⁸, R⁹, and R¹⁰.

10. The examined subject matter is as follows:

A compound of formula I wherein A is aryl; R⁵ is -C(O)OR⁵⁵; and one of R², R⁸, R⁹, and R¹⁰ is -OR⁴³. The radicals not defined herein are defined according to claim 1. Amending the claims to the examined subject matter would overcome the improper Markush rejection.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

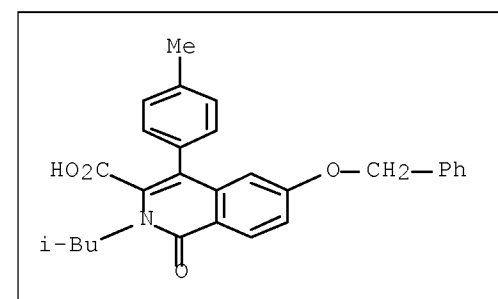
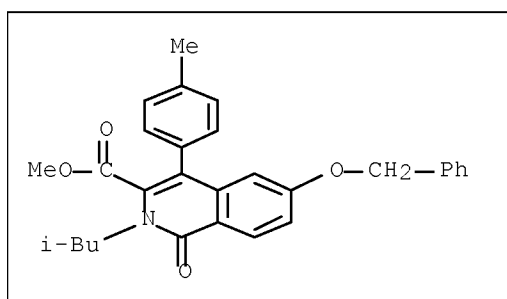
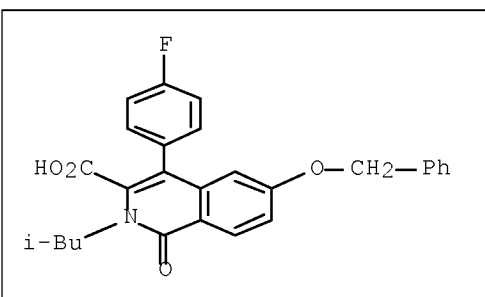
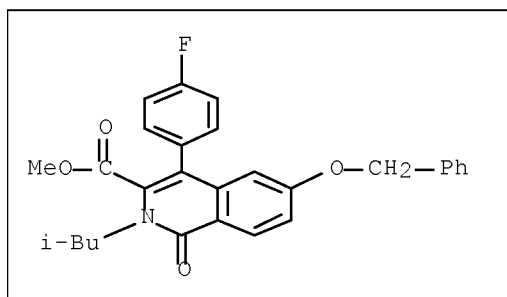
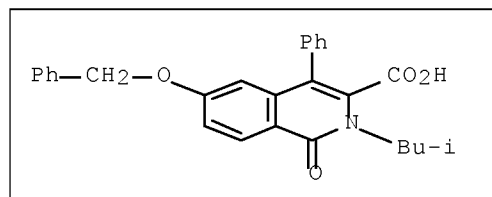
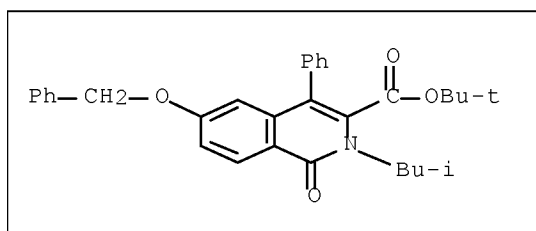
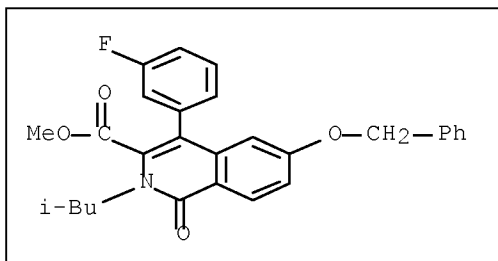
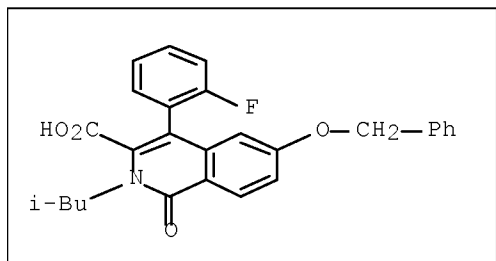
(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-6, 19, and 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Takeda Chemical Industries, Ltd. (Reference N, cited by the Examiner).

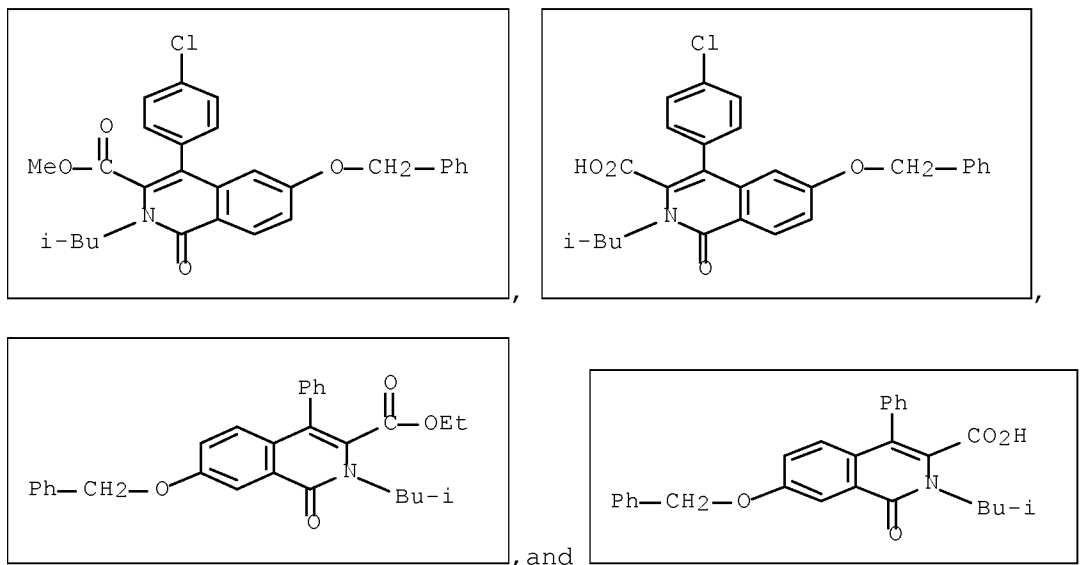
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The instantly claimed compounds are disclosed. At page 83, see formula II-b.

For instance, at page 360, see lines 18-19. The compounds are depicted below:



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13. Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. The Information Disclosure Statement filed June 12, 2006 has been considered.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.

16. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communications.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Zinna Northington Davis/
Zinna Northington Davis
Primary Examiner
Art Unit 1625

Znd
06.08.2009